

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-60 were pending in this application when last examined.

Claims 34-37 were examined on the merits and stand rejected.

Claims 1-33 and 48-60 were withdrawn.

Claim 36 was also objected.

Claim 34 has been amended to better conform with US practice and to clarify that the charge control agent in step 1 has a negative charge in solution and is capable of specifically binding to the target particle in the sample. Support can be found in the disclosure, for example, at page 8, lines 20-24, page 16, lines 1-3 and original claim 34.

Claim 34 has also been amended to incorporate the subject matter of claims 37, 42 and 47.

Claims 35 and 36 have been amended to recite "plurality of target particles." Support can be found in the claims as filed.

Claim 36 has also been amended to correct a punctuation error by adding a comma after "agents" in line 3. Support can be in the claim as filed.

Therefore, no new matter has been added by this amendment to the claims.

Claims 37-47 have been canceled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Claims 1-36 and 48-60 are pending upon entry of this amendment.

Enclosed herein is a revised substitute specification. The specification has been revised to correct the improper use of trademarks noted at the bottom of page 3 of the Action. Support can be found in the specification as filed.

The specification has also been amended at page 15 to separately list Fig. 1A and Fig. 1B in the "Brief Description of the Drawings" section. Support can be found at page 17, lines 9-12 in the specification as filed.

Therefore, no new matter has been added by this amendment to the specification.

II. CLAIM OBJECTION

In item 7 on page 4 of the Office Action, claim 36 was objected to for lacking a comma after the word "agents" in line 3.

The present amendment overcomes this claim objection for reasons which are self-evident.

III. INDEFINITENESS REJECTIONS

In items 9-15 on pages 4-5 of the Action, claims 34-47 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

It is respectfully submitted that the present amendment overcomes this rejection.

Claim 34 has been amended to better conform with US practice and to clarify that the charge control agent in step 1 has a negative charge in solution and is capable of specifically binding to the target particle in the sample as supported by the disclosure at page 8, lines 20-24 and page 16, lines 1-3. In view of this amendment, it is respectfully submitted that one skilled in the art would understand the metes and bounds of the claimed invention.

Claim 34 has also been amended to delete the objected term "resulting from the mixture", thereby overcoming the concern in item 11 on page 5 of the Action.

Claims 35 and 36 have been amended to recite "plurality of target particles", thereby overcoming the concern in item 12 on page 5 of the Action.

With regard to "charge control agents" in claim 36, it is respectfully submitted that the such language refers to the respective "plurality target particles" in the claim.

The present amendment cancels claims 37-47, thereby obviating the rejections of claims 40, 42, 43, and 45 set forth in items 14-15 on pages 5-6 of the Action.

Therefore, the rejection of claims 34-47 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

IV. ANTICIPATION REJECTION

In item 17 on page 6 of the Action, claims 34-39, 41-44 and 46 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kopf-Sill et al. (US 6,524,790).

This rejection is respectfully traversed as applied to the amended claims.

To anticipate a claim, a cited prior art reference must teach each and every element of the claimed invention. M.P.E.P. § 2131.01.

Prior to the present invention, conventional methods, such as electrophoresis, were known and used for separating particles having charges, such as cells or bacteria. However, it is very difficult to separate target particles from other materials in a sample based on inherent charges of the target particles.

The present invention, as recited in amended claim 34, includes a novel feature of adding charges externally to the target particles.

In particular, amended claim 34 calls a method of separating or quantitatively determining a target particle in a sample, comprising the steps of:

mixing a sample containing the target particle and a charge control agent, which has negative charge in solution and is capable of specifically binding to the target particle in the sample, and binding the charge control agent to the target particle; and

separating or quantitatively determining the target particle provided with the charge control agent bound thereto, based on a surface charge modified by the binding of the charge control agent, by applying a voltage or current to the mixed solution comprising the sample and the charge control agent, wherein

the target particle is a cell selected from the group consisting of white blood cell, lymphocyte, platelet, and red blood cell, or a microorganism selected from the group consisting of bacterium, virus, and fungus,

the charge control agent is a complex composed of an antibody and a marker dye, which are bound together, wherein the antibody is capable of specifically binding to a biological functional substance, and

the dye is aminoethyl4-azidebenzamide trisodium salt or N-(3-triethylammoniumpropyl)-4-(4-di-octadecylamino) styryl) pyridiniumdi-4-chlorobenzenesulfonate.

Specifically, in the method of amended claim 34, a charge control agent is prepared as a complex composed of an antibody and a dye, which are bound together. Subsequently, the charge control agent is mixed with a sample containing target particles to be separated in order to give negative charges to the target particles. The dye specified in amended claim 34 has three sulfonic acid groups, and therefore, can notably change charges on the surface of target particles to be negative.

It is respectfully submitted that the recited prior art, in particular, the primary reference of Kopf-Sill, fails to disclose or suggest the dye recited in amended claim 34. For example, Kopf-Sill discloses a fluorescent dye, which may be used as a label. However, the label is used for spectroscopic measurements. See column 27, lines 65-67 of Kopf-Sill. Therefore, the label in Kopf-Sill is not used for giving charges to target particles. Therefore, the teaching in Kopf-Sill differs from that of the present invention in view of the object of using the label and an effect obtained by using the label.

Thus, since Kopf-Sill fails to disclose or suggest the dye recited in amended claim 34, Kopf-Sill cannot anticipate the present invention.

Therefore, the rejection of claims 34-39, 41-44 and 46 under 35 U.S.C. § 102(e) is untenable and should be withdrawn.

V. OBVIOUSNESS REJECTIONS

In item 20 on page 9 of the Action, claims 40 and 45 were rejected under 35 U.S.C. § 103(a) as obvious over Kopf-Sill et al. in view of Janjic et al. (US 6,329,145).

In item 21 on page 10 of the Action, claim 47 was rejected under 35 U.S.C. § 103(a) as obvious over Kopf-Sill et al. in view of Molnar et al. (Biochemica et Biophysica Acta, 1991, vol. 1068, pp 27-40) and further in view of Whitaker et al. (Analytical Biochemistry, 1991, vol. 198, pp 119-130).

The rejected claims have been cancelled. Therefore, the above-noted obviousness rejections under 35 U.S.C. § 103(a) are untenable and should be withdrawn.

VI. OBJECTION TO THE DRAWINGS

In item 5 on page 2 of the Action, the drawings were objected to on the basis that Fig. 1A and Fig. 1B must be listed separately in the "Brief Description of the Drawings" section of the specification.

However, kindly note that, even though it was indicated that the Drawings were objected to, the Action fails to note any errors in the Drawings/Figs. themselves. Thus, it appears that the Office intended to object to the specification, as opposed to the Drawings.

In this regard, the specification has been amended to overcome this objection by separately listing Fig. 1A and Fig. 1B in the "Brief Description of the Drawings" section. Accordingly, the present amendment overcomes the objections noted in the Action.

Therefore, the above-noted objection is untenable and should be withdrawn.

VII. OBJECTION TO THE SPECIFICATION

In item 6 on page 3 of the Action, the specification was objected to for not complying with the rules of U.S. practice for the use of trademarks in a specification.

Attached herewith is revised substitute specification with corrections therein. The specification has been revised to correct the errors noted by the Examiner at the bottom of page 3 of the Action.

Therefore, the objection to the specification is untenable and should be withdrawn.

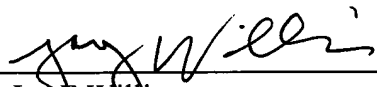
CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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ATTACHMENTS

1. Revised substitute specification, including marked-up version and clean copy.